Testimony of

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"Managing Biomedical Research to Prevent and Cure Disease in the 21st Century: Matching NIH Policy with Science"

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Mr. Chairmen and Members of the Committees:

I appear here today as a former Director of the National Institutes of Health, a position I held from November, 1993, until the end of 1999. For the record, I am currently the President and CEO of the Memorial Sloan-Kettering Cancer Center in New York City; I received the Nobel Prize in Physiology or Medicine with Dr. J. Michael Bishop in 1989 for studies of cancer genes conducted over several years at the University of California, San Francisco; and I serve as Chairman of the Joint Steering Committee for Public Policy, a group representing several scientific societies.

I would like to begin with a few general observations about the NIH. I was trained as a scientist in the NIH intramural program, my research as a faculty member was supported by NIH grants, and I was given the privilege of leading the agency for over six years. Throughout my career and especially during my tenure as Director, I have unwaveringly admired the NIH as an effective force for good in the world, one created and fostered by our government, and thus a source of pride for all Americans. Of course, I am not alone in this opinion. The nearly universal reverence in which the NIH is held can be attributed to several things: its long history of discovery and progress against disease; its diverse programs in research, training, and communication of new knowledge; its essential contributions to the vitality of some of our greatest institutional resources, including our universities, medical schools, and health-oriented industries; the multitude of disciplinary approaches with which it pursues better health through science; and the rigorous, competitive review processes it uses to evaluate and insure the high quality of all of its scientific activities.

For these reasons, our country's leaders have traditionally provided non-partisan and enthusiastic support for the budget and the programs of the NIH. This support has allowed the agency to retain the spirit and excellence of an intellectual community in the setting of government; to recruit many of the nation's best physicians and scientists to serve as Directors of Institutes and Centers (ICs), research administrators, and intramural laboratory personnel; and to perform in a fashion that justifies the hopes of the public and Congress and incites envy in many other countries around the world.

This enthusiasm for the NIH has helped to double its budget over the past five years and to create an environment in which expectations of future

progress exceed its remarkable past achievements. The human genome and the genomes of many other organisms have been read at unanticipated speed; new and powerful tools for analysis of genes, cells, and intact organisms have been developed; many brilliant people have been trained in biology and related sciences; and academic institutions have invested in new programs and buildings to exploit new knowledge and advance health. These opportunities are matched by obvious needs---those created by our aging population and the prospects of prolonged disability; by new concerns about emerging infectious diseases and bio-terrorism; by persistent, unacceptable levels of disease both in developing countries and among the less affluent citizens of our own; and by the rising costs of health care. For these reasons and others, we need a strong NIH, now more than ever, if we are to confront these issues and seize the recently created opportunities.

Although the NIH is a strong agency, it is not perfect. Because it is strong, we should undertake changes only with caution. But because we should also strive for perfection, it is appropriate that we consider what should be done to make the NIH even better than it is. To that end, I would like to describe three goals that I would recommend for your consideration in any legislative effort to reform or reauthorize the agency.

1) Counter the deleterious effects of IC proliferation.

The continued growth of the number of Institutes and Centers at the NIH has complicated management of the agency, especially at a time when scientific opportunities call for more coordination among IC's to develop large, expensive, multi-disciplinary programs.

During my final year as Director of the NIH, I began to discuss publicly my concerns about the detrimental effects of the growing numbers of ICs on the planning, management, and funding of NIH's scientific programs. I argued then and would argue now that the continued proliferation of NIH ICs---presently 27, with a recent birth rate of about five per decade---threatens the capacity of the agency to seize important opportunities and undermines the ability of the NIH Director to lead. While acknowledging that enthusiastic advocacy for many individual ICs has budgetary advantages for the NIH and that a significant reduction in their number would be politically difficult and even perilous, I proposed a path to a more manageable and efficient agency

by fusing the existing institutes into five large units, led by Institute Directors, and a sixth unit, NIH Central, led by the NIH Director. (These ideas are explained more fully in an article in Science magazine, volume 291, pages 1903-1905, March 9, 2001; see http://www.sciencemag.org/cgi/content/full/291/5510/1903).

By the time the Science article appeared, Congress had directed the NIH to fund a National Research Council (NRC) study of the organization of the agency. (Dr. Harold Shapiro, who led that study, will review its findings and recommendations with you shortly; I would be pleased to comment on the study in response to questions.)

While I accept the NRC panel's conclusion that widespread fusion of IC's is impractical and perhaps inappropriate at this time, I continue to believe that steps must be taken to overcome the effects of Balkanization at the NIH on the planning and support of its scientific programs. There are several reasons for this. It is very difficult if not impossible to conduct strategic planning routinely with twenty seven IC Directors and several Deputy Directors of the NIH. Existing ICs vary greatly in the size of budget and staff, so that many cannot afford to carry out important programs entailing the clinical, multi-disciplinary, or technologically sophisticated research required by modern biomedical science. All ICs are understandably protective of existing resources and programs, making collective efforts difficult to initiate and maintain, especially when budgetary increases are small, as seems likely to occur in the immediate years ahead.

What steps, short of IC fusions, can be taken? The current NIH Director, Elias Zerhouni, has recently completed a Herculean planning process to produce the just-announced NIH Road Map, a highly commendable blueprint for coordinated efforts---in technology development, interdisciplinary training, and clinical research---to which all ICs have pledged to contribute. However, this remarkable achievement is unlikely to be regularly reproduced.

I suggest a few steps to simplify inter-IC program planning and more efficient use of resources in the future. (a) Authorize the formation of "clusters" of ICs to propose and fund large, mutually beneficial initiatives. Although the composition of "clusters" should be subject to further discussion, one possible arrangement would conform to the five fusions I proposed earlier. (b) Provide financial incentives to ICs that develop and

support coordinated efforts. (c) Use the "clusters" to achieve administrative efficiencies (e.g. in personnel management and procurement functions) and consolidate intramural research programs, in the fashion illustrated by the Neuroscience Initiative now underway on the NIH campus in Bethesda. (d) Establish legislative barriers to the creation of new ICs by requiring an extensive review process that guarantees a well-documented need for any newly authorized unit.

2) Augment the authority of the NIH Director.

As discussed in the preceding section, the NIH is organizationally complex and difficult to lead. Regardless of the methods that are used to control the number of ICs or to encourage collaboration among the ICs, it is time to consider measures that would provide the NIH Director with a stronger role in research planning. This would improve the management of the agency and make the Director's job more attractive to prospective candidates.

I envision several ways to do this. (a) The NIH Director should be given greater discretionary authority over the appropriated budgets of the ICs, so that he or she can encourage the kinds of inter-IC or trans-IC programs mentioned above. (This could be achieved with a larger Discretionary Fund, an enhanced Transfer Authority, or a larger direct allocation to the Office of the Director, with the option of later transferring those funds to ICs for project management and continued support.) (b) The Office of the Director (OD) should be enlarged to include a cohort of scientist-administrators who could take a more active role in the planning of research programs in concert with the ICs. These individuals, who might be short-term government employees on leave from academic or industrial positions, would be responsible for proposing and initiating innovative research programs that would ultimately be transferred to one or more ICs. (c) The NIH Director would be authorized to assemble a small group of IC Directors to serve as an Executive Committee to plan new initiatives. The members of this group would ideally represent the thematic "clusters" of ICs described earlier and serve limited terms on the committee. (d) To optimize the planning process and avoid uncertainties in status, all ICs and their Directors would have the same authorities. To achieve this, the special privileges conferred upon the National Cancer Institute would need to be reversed by Congress, as also recommended by Dr. Shapiro's panel. I also support the panel's suggestion that IC Directors serve fixed terms, with the option of renewal.

3) Insulate the NIH from partisan politics.

NIH is a creation of government and is appropriately subject to oversight by the Executive and Congressional branches. But it works best when the selection of its leadership and advisors, the review of its operations, and the allocation of its fiscal support are based on performance, scientific needs, and public health objectives that can be endorsed by both parties.

Several means can be considered to re-enforce the traditional bipartisan approach to the NIH. I have long supported the idea that the NIH Director should be appointed for a fixed term of about six years, with the option of an additional term, to separate the selection of a Director from electoral politics. Second, the selection of the Director of the NCI should be conducted in the same manner as the selection of other IC Directors, in accord with my earlier recommendation that the NCI be treated like the other ICs. Third, Congress should endorse the concept that members of Advisory Councils and other review panels should be selected on the basis of their knowledge of the medical and scientific issues faced by the NIH and its components, not as rewards for political views or favors.

In closing, I would like to thank the members of this Joint Committee for undertaking a careful review of the NIH and for conducting this hearing. As I have emphasized, the NIH is a remarkable agency, and it offers an unusual opportunity for constructive oversight. Any beneficial actions will be applauded widely by a public eager for the government's support of advances against disease.

I would be pleased to try to answer any questions you might have.